GNE.3030R1C5

**PATENT** 

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Goddard et al. (as amended)

Appl. No.

10/036,342

Filed

December 26, 2001

For

POLYPEPTIDES THAT INDUCE

CELL PROLIFERATION (as

amended)

Examiner

Kolker, Daniel E.

Group Art Unit

1649

## **DECLARATION UNDER 37 CFR §1.131**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

We declare and state as follows:

- 1. We are the inventors of the invention claimed in the above-captioned patent application.
- 2. During the time period in which we participated in the events and activities described herein, we were employed by Genentech, Inc., the assignee of the above-captioned application.
- 3. All of the events and activities described herein were performed by us personally, or by others at our direction as part of our duties as employees of Genentech, Inc.
- 4. The invention claimed in the above-captioned patent application was conceived and reduced to practice in the United States prior to November 10, 1999 as described below.
- 5. Prior to November 10, 1999, we conceived of the invention claimed in the above-captioned patent application. This is demonstrated by the attached sequence printout (Exhibit A), which was generated prior to November 10, 1999, and which shows the complete sequence of the nucleic acid having the sequence of SEQ ID NO: 56. The attached printout also shows the complete sequence of the polypeptide which has the sequence of SEQ ID NO: 57. As evidenced by the sequence printout, we were in possession of the complete nucleic acid and amino acid sequences prior to November 10, 1999.
- 6. The date deleted from Exhibit A is prior to November 10, 1999. This date was redacted pursuant to M.P.E.P. § 715.07. The date that remains is the date the report was printed, April 28, 2005.
- 7. After these initial experiments, we diligently reduced the claimed subject matter to practice by working to express and purify the encoded polypeptide and to run it systematically

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through many assays. The cDNA was deposited with the American Type Culture Collection (ATCC) on April 20, 1999 and assigned ATCC no. 203948. The protein of interest was assigned a "protein inventory number" (e.g., PIN1205-1), and this protein is a polypeptide having the sequence of SEQ ID NO:57, and is encoded by SEQ ID NO: 56.

- 8. Exhibit B shows that the protein lot designated PIN1205-1 was delivered to James Pan on a date prior to November 10, 1999 in order to perform assay ASY92, called "Mouse Mesangial Cell proliferation Assay." Also, as shown in Exhibit B, the assay was completed on a date prior to November 10, 1999. Exhibit B also shows that the tested polypeptides tested positive ("All Positives"), thereby confirming the ability of the encoded polypeptide to induce mesangial cell proliferation. Thus, actual reduction to practice occurred on a date prior to November 10, 1999.
- 9. The dates deleted from Exhibit B all are prior to November 10, 1999. These dates were redacted pursuant to M.P.E.P. § 715.07. The date that remains is the date the report was printed, April 28, 2005.
- After reducing the invention to practice, we worked with the Genentech, Inc. patent department to prepare a non-provisional patent application, which included the sequences of SEQ ID NO:56 and SEQ ID NO:57, as well as the data showing the ability to induce mesangial cell proliferation. That application was filed on March 1, 2000 as PCT/US00/05601.
- 11. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

Ву: _	Audrey Goddard	Date: 19 007 05
Ву: _	Paul J. Godowski	Date:
Ву: _	Austin L. Gurney	Date:
	James Pan	Date:
Ву: _	Colin K. Watanabe	Date:
Ву: _	William I. Wood	Date:

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By: _		Date:
Ву:	Andrey Goddard	Date: 10 18 05
Ву:	Austin L. Gurney	Date:
Ву:	James Pan	Date:
Ву:	Colin K. Watanabe	Date:
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By:	Date:
Paul J. Godowski	Date
By:	Date:
Austin L. Gurney	
By:	Date: Oct 24/05-
By: Colin K. Watanabe	Date:
Ву:	Date:
William I. Wood	
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Ву: _	Coln K. Watander	Date: Cst 20, 245
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